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10/505,153	03/14/2005	Mikio Suzuki	Q82789	5702
23373 7590 07/03/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER GIBBS, TERRA C	
			ART UNIT 1635	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,153

Applicant(s)

SUZUKI ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed March 14, 2005.

Claims 13-17, 31-33, 25, and 38 have been amended.

Claims 1-40 are pending.

Claims 1-40 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, 17, 18, 35, 38 drawn to a polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1, classifiable in class 536, subclass 24.5, for example.
- II. Claims 1-15, 17, 18, 35, 38, drawn to a polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2, classifiable in class 536, subclass 24.5, for example.
- III. Claim 16, drawn to a method for screening pharmaceutical product gene

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target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1, classifiable in class 435, subclass 6, for example.

- IV. Claim 16 drawn to a method for screening pharmaceutical product gene target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:2, classifiable in class 435, subclass 6, for example.
- V. Claims 19-32, 36, 37, drawn to a method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:1, classifiable in class 514, subclass 44, for example.
- VI. Claims 19-32, 36, 37, drawn to a method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous

components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2, classifiable in class 514, subclass 44, for example.

VII. Claims 33 and 34, drawn to a knockdown cell or tissue or a non-human knockdown animal or a knockdown plant produced and cultured by the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1, classifiable in class 800, subclass 295, for example.

VIII. Claims 33 and 34, drawn to a knockdown cell or tissue or a non-human knockdown animal or a knockdown plant produced and cultured by the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression

activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2, classifiable in class 800, subclass 295, for example.

- IX. Claim 39, drawn to a method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b) synthesizing component (III) based on nucleotide synthesis enzyme activity, classifiable in class 435, subclass 91.1, for example.
- X. Claim 40, drawn to a nucleotide for a randomized target gene obtained by the method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b) synthesizing component (III) based on nucleotide synthesis enzyme activity, classifiable in class 536, subclass 23.1, for example.

The inventions are distinct, each from the other, because of the following reasons:

Group I is related to Groups III and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1 of Group I can be used in a materially different process such as a hybridization probe in a method of identifying gene mRNA expression *in situ*, which is a materially different process than the method for screening pharmaceutical product gene target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1 of Group III or the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:1 of Group V. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Group II is related to Groups IV and VI as product and process of use. The

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inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2 of Group II can be used in a materially different process such as a hybridization probe in a method of identifying gene mRNA expression *in situ*, which is a materially different process than the method for screening pharmaceutical product gene target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2 of Group IV or the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:2 of Group VI. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required

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because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Group X is related to Group IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleotide for a randomized target gene obtained by the method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b) synthesizing component (III) based on nucleotide synthesis enzyme activity of Group X can be used in a materially different process such as a hybridization probe in a method of identifying gene mRNA expression *in situ*, which is a materially different process than the method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b) synthesizing component (III) based on nucleotide synthesis enzyme activity of Group IX. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Groups I and II are directed to related inventions. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are

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mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) of Groups I and II are mutually exclusive because each polynucleotide sequence of each Group comprises a different nucleic acid sequence. For example, Group I is drawn to a polynucleotide sequence comprising a single stand of sequence synthesized uGL3.12RNA (SEQ ID NO:1), while Group II is drawn to a polynucleotide sequence comprising a single stand of sequence synthesized uGL3.7RNA (SEQ ID NO:2). Moreover, the polynucleotides of Groups I and II are not disclosed as obvious variants and are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Groups III and IV are directed to related inventions. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand

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polynucleotide sequence comprising continuous components (I) + (II) + (III) of Groups II and IV are mutually exclusive because each polynucleotide sequence of each Group comprises a different nucleic acid sequence. For example, Group III is drawn to a method of using polynucleotide sequence comprising a single stand sequence synthesized uGL3.12RNA (SEQ ID NO:1), while Group IV is drawn to a method of using a polynucleotide sequence comprising a single stand of sequence synthesized uGL3.7RNA (SEQ ID NO:2). Moreover, the method of using the polynucleotides of Groups III and IV are not disclosed as obvious variants and are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Groups V and VI are directed to related inventions. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) of Groups VI and VI are mutually exclusive because each polynucleotide sequence of each Group comprises a different nucleic acid sequence. For example, Group V is drawn to a

method of using a polynucleotide sequence comprising a single stand sequence synthesized uGL3.12RNA (SEQ ID NO:1), while Group VI is drawn to a method of using a polynucleotide sequence comprising a single stand of sequence synthesized uGL3.7RNA (SEQ ID NO:2). Moreover, the method of using the polynucleotides of Groups V and VI are not disclosed as obvious variants and are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Groups VII and VIII are directed to related inventions. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the knockdown cell or tissue comprising the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) of Groups VII and VIII are mutually exclusive because each polynucleotide sequence of each Group comprises a different nucleic acid sequence. For example, Group VII is drawn to knockdown cell or tissue comprising a polynucleotide sequence comprising a single stand sequence synthesized uGL3.12RNA (SEQ ID NO:1), while Group IV is drawn to knockdown cell or tissue comprising polynucleotide sequence

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comprising a single stand of sequence synthesized uGL3.7RNA (SEQ ID NO:2). Moreover, the knockdown cells or tissues comprising the polynucleotides of Groups VII and VIII are not disclosed as obvious variants and are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Group III is drawn to a method for screening pharmaceutical product gene target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:1 and is considered to be distinct from the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:1 of Group V or the method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b) synthesizing component (III) based on nucleotide synthesis enzyme activity of Group IX. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

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inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group III is distinct from the methods of Groups V and IX since each of the methods recite distinct method steps and distinct objectives. Furthermore, Group III is distinct from Groups V and IX since the Groups do not overlap in scope as each Group recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

Group IV is drawn to a method for screening pharmaceutical product gene target genes using the polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein the target gene comprises a single strand of RNA of SEQ ID NO:2 and is considered to be distinct from the method for introducing an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III) into cells or tissues, and to suppress the function of a target gene, protein, or activity of a transcript of a target gene based on an RNA function suppression activity of a gene having a sequence complementary to the polynucleotide sequence of either of the component (I) or (III) in cells or tissues, wherein the target gene comprises a single strand of RNA of SEQ ID NO:2 of Group VI or the method for synthesizing nucleotides for target genes including the steps of (a) preparing a single strand nucleotide comprising component (I and (II) and (b)

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synthesizing component (III) based on nucleotide synthesis enzyme activity of Group IX. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group VI is distinct from the methods of Groups VI and IX since each of the methods recite distinct method steps and distinct objectives. Furthermore, Group IV is distinct from Groups VI and IX since the Groups do not overlap in scope as each Group recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

If either of Groups I, II V, or VI are elected, claims 11 and 29 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*,

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580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 11 and 29 specifically claims compositions or methods of using compositions comprising a polynucleotide sequence which is a polynucleotide sequence for a target gene comprising an isolated or purified single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein component (II) is indicated by SEQ ID NO: 3 or 4. Although the sequences claimed are each component sequences, the instant sequences are considered to be unrelated, since each component sequence claimed is structurally and functionally independent and distinct for the following reasons: each component has a unique nucleotide sequence, namely a component sequence of uGL3.12 RNA or uGL3.7 RNA, respectively. As such the Markush/genus of component sequences listed in claims 11 and 29 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the component sequences claimed in claims 11 and 29 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed component sequences. In view of the foregoing, one (1)

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component sequence is considered to be a reasonable number of sequences for examination. Accordingly, Applicants are required to elect one (1) component sequence from claims 11 and 29. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct component sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg

June 22, 2007

/Terra Cotta Gibbs/